

<b>LIST OF REFERENCES CITED BY APPLICANT</b> (Use several sheets if necessary)	ATTY DOCKET NO.	APPLICATION NO.
	Y2428-00163	10/510,673
	APPLICANT Brogmann et al.	
	FILING DATE	GROUP
	May 23, 2005	1615

### U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A06	4,126,684	11/21/1978	Robson et al.			
	A07	4,668,685	05/26/1987	Shami			
	A08	5,236,714	08/17/1993	Lee et al.			
	A09	6,258,042	07/10/2001	Factor et al.			
	A10	6,696,088	02/24/2004	Oshlack et al.			
	A11	2003/0178031	09/25/2003	DuPen et al.			
	A12	2007/0185146	08/09/2007	Fleischer et al.			

### FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	B14	2138593	03/30/1972	DE				
	B15	1604666	12/14/2005	EP				
	B16	1353815	05/22/1974	GB				
	B17	1999/005960	02/11/1999	PCT				
	B18	2001/058447	08/16/2001	PCT				
	B19	2002/087512	11/07/2002	PCT				
	B20	2002/092060	11/21/2002	PCT				
	B21	2003/020124	03/13/2003	PCT				
	B22	2003/073937	09/12/2003	PCT				
	B23	2003/084504	10/16/2003	PCT				
	B24	2003/084520	10/16/2003	PCT				

### OTHER REFERENCES *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	C09	Clark et al., "Symptom indexes to assess outcomes of treatment for early prostate cancer" <u>Medical Care</u> 39(10): 1118-1130 (October, 2001).
	C10	Cohen, <u>Statistical Power Analyses for the Behavioral Sciences</u> (2 <sup>nd</sup> ed.) Hillsdale, NJ: Erlbaum (1988)
	C11	Deyo RA et al., "Reproducibility and responsiveness of health status measures. Statistics and strategies for evaluation." <u>Cont. Clin. Trials</u> 12: 142S-158S (1991).
	C12	Drossman DA et al., <u>Rome II: The Functional Gastrointestinal Disorders</u> (2 <sup>nd</sup> ed.) McLean, VA: Degnon Associates (2000)
	C13	Guyatt et al., "Measuring change over time: assessing the usefulness of evaluative instruments" <u>J. Chronic Dis.</u> 40(2): 171-178 (1987).
	C14	Guyatt et al., "Interpreting treatment effects in randomized trials" <u>Br. Med. J.</u> 316(7132): 690-693 (1998).
	C15	Hays et al., "Assessing reliability and validity of measurement in clinical trials" in: Staquet et al., (eds.) <u>Quality of Life in Clinical Trials: Methods and Practice</u> Oxford: Oxford University Press (1998).
	C08	Hussain, MA, "Improved buccal delivery of opioid analgesics and antagonists with bitterless prodrugs" <u>Pharm. Res.</u> 5(9): 615-618 (1988).
	C16	Kazis et al., "Effects sizes for interpreting changes in health status" <u>Med. Care</u> 27(3 Suppl.): S178-S189 (1989).
	C17	Leidy et al., "Recommendations for evaluating the validity of quality of life claims for labelling and promotion" <u>Value in Health</u> 2(2): 113-127 (1999).

	C18	Norman et al., "Interpretation of changes in health-related quality of life. The remarkable universality of half a standard deviation" <u>Med. Care</u> 41: 582-592 (2003).
	C19	Nunnally et al., <u>Psychometric Theory</u> (3 <sup>rd</sup> ed.) NY: McGraw-Hill (1994).
	C20	Revicki et al., "Recommendation on health-related quality of life research to support labelling and promotional claims in the United States" <u>QOL Research</u> 9(8): 887-900 (2000).
	C21	Wyrwich et al., "Further evidence supporting an SEM-based criterion for identifying meaningful intra-individual changes in health-related quality of life" <u>J. Clin. Epidemiol.</u> 52: 861-873 (1991).
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with <b>MPEP 609</b>; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>		